

REMARKS

The claims are 1, 8-10, 12-14, 16 and 18-22, with claim 1 being the sole independent claim. Claims 2-7, 11, 15 and 17 have been cancelled without prejudice or disclaimer. Support for Claim 18 may be found in Claim 14. Support for claims 19-22 may be found in the specification at page 9, 2<sup>nd</sup> paragraph, lines 8-15. No new matter has been added.

The specification has been amended to insert the trademarks GELUCIRE® 50/13, 44/14, 50/02 and PRECIROL® ATO 5.

Claim 14 was rejected under 35 U.S.C. 112, first and second paragraphs and Claims 1, 8-10, 12-14, and 16 were rejected under 35 U.S.C. 103(a). Applicants respectfully traverse each of these rejections.

Claim 14 has been amended to recite treatment and/or prophylaxis of the glucose metabolism disorders of diabetes mellitus and metabolic syndrome. New claim 18 is directed to the treatment of Alzheimer's disease. Provided in the IDS submitted herewith are the label and clinical trial reports that indicate 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (administered as the maleate salt) is effective at improving mentation in patients with Alzheimer's Disease, treating hyperglycemia, and delaying the onset of Type 2 diabetes.

Claims 1, 8-10, 12-14, and 16 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Patel et al. (U.S. Patent No. 6294192 B1) and Hindley et al. (U.S. Patent No. 6,288,095 B1). Applicants respectfully submit that none of the cited references disclose or suggest a pharmaceutical composition containing a stable polymorphic form of a macrogol glyceride, or any method of preparing the same.

As described in the specification (page 9, 2<sup>nd</sup> paragraph), certain macrogol glycerides exist in more than one polymorphic form. The inventors found that by heat treating the oral dosage forms at a temperature below the melting point of the carrier after moulding and coating tablets (or filling capsules), the macrogol glyceride could be converted to its more stable form. This also results in a significant reduction in variability of the dissolution profile between individual oral dosage forms (see Table 2), which provides a significant advantage in accurate dosing.

Reconsideration and withdrawal of the Section 103 rejection is respectfully requested.

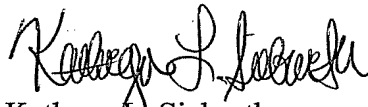
Applicants respectfully submit that the subject application is in condition for allowance. If the Examiner has any remaining objections or concerns, the Examiner is

Appln. No.: 10/576,403  
Group Art Unit No.: 4131

respectfully requested to contact Applicants' undersigned agent to resolve such issues and advance the case to issue.

Authorization to charge any fees under 37 C.F.R. §1.16 or §1.17 which may be required by these papers to Deposit Account No. 19-2570.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Kathryn L. Sieburth', written in a cursive style.

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